DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

February 17, 2015

Handpiece Headquarters
Mr. Sonny Phung
Product Engineer
620 S. Placentia Ave.
Placentia, CA 92870

Re: K143183
Trade/Device Name: Maxima XTEND Handpiece Maintenance System
Regulation Number: 21 CFR 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EFB
Dated: December 2, 2014
Received: December 3, 2014

Dear Mr. Phung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K143183

Device Name: **Maxima XTEND Handpiece Maintenance System**

Indications for Use:

The Maxima XTEND Handpiece Maintenance System is intended for cleaning and lubrication of dental Handpieces including air turbines, air motors and air driven scalers prior to sterilization.

Prescription Use X AND/OR Over-The-Counter Use
(Per 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

K143183

510(K) SUMMARY:

Reference: 510(k) Traditional Premarket Notification for Maxima XTEND Handpiece Maintenance System.

a- Submitted by: HANDPIECE HEADQUARTERS
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b- Contact person: Sonny Phung
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c- Date summary prepared: 12-02-2014

d- Device Name:

Trade or Proprietary Name: Maxima XTEND Handpiece Maintenance System

Common Name: Dental Handpiece and accessories (Lubricant)

Classification Name: Dental Handpiece and accessories

Classification number: (21CFR 872.4200)

Class: I

Product Code: EFB

e- Substantial Equivalency is claimed against the following device:

STATMATIC 31 Handpiece Maintenance Unit by SciCan LTD.
510(k) # K073319

f- Description of the device:

Maxima XTEND Handpiece Maintenance System is a complete automatic dispensing system for cleaning; lubrication and purging old oil for dental handpieces prior to sterilization cycles.

User can use push button key pad to select time for purging lubricant into handpiece including 15 seconds, 20 seconds, and 30 seconds. In addition, there are 11 adjustable settings for the amount of lubricant into the handpiece; user can choose the amount of lubricant to purge into handpieces accordingly. The system can maintenance up to 3 handpieces at the same time, and an unique chuck care nozzle to lubricate chucks in dental turbines.

Service Maxima XTEND Handpiece maintenance system is capable to operate with aerosol lubricant can with or without compressed-air supply. Air pressure will deliver Lubricant directly through internal parts of handpieces and contra angles by the controlling of software to open and close magnetic valves. The system will purge all the excess lubricant. The provided linen pads and removable trays on front side and bottom of the system will absorb the excess liquid of lubricant.

Lubricant uses for the Maxima Handpiece Maintenance System is aerosol spray can “Maxima Handpiece Cleaner & Lubricant” has been previous cleared with 510(k) # K113674

The Maxima XTEND Handpiece Maintenance System contains following main components:

1 Main case
2 Rear case
3 Front door module
4 PCBA board
5 Power supply
6 Adapters module
7 LCM Module
8 Oil supply module
9 Solenoid valve
10 Rear components module
11 Back plate cover
12 Top cover
13 Veneer (Bright Blue)
14 Oil tray
15 Rotation motor module

g- Statement of Intended Use:

The Maxima XTEND Handpiece Maintenance System is intended for cleaning and lubricating of dental handpieces including air turbines, air motors and air driven scalers

prior to sterilization.

H-comparison of technological characteristics:
1-comparsion table:

FEATURES	MAXIMA XTEND HANDPICE MAINTENANCE SYSTEM	SCICAN STATMATIC (K073319)
Number of connections	4	4
Build in chuck adaptor	yes	Yes
Cycle times to lubricate handpiece	15,20,25 seconds programmable	15 Seconds
Lubricant change indicator	yes	Yes
Lubricant containment	Maxima Handpiece cleaner& lubricant- Aerosol can- 510(k) # K113674	STATMATIC SPRAY Aerosol can
Compress air	58-87 psi.	58-87 psi.
Air consumption	40 NL/min	40 NL/min
Dimensions	295x385x295 mm (11.6 x 15.15 x 11.6 in.)	285x190x400 mm (11.2 x 7.5 x 15.8 in.)
Weight	9.0 Kg (19.8 Lbs.)	8.6 Kg (18.96 Lbs.)
Warranty	5 years	10 Years

2-Comparison of performance testing:

Based on product testing results in attachment 3; there are no significant changes in performance of testing handpieces after 250 cycles of testing by using Maxima XTEND and STAMATIC 31 Handpiece Maintenance Unit. The performance of these handpieces including speed, torque bur extraction force and concentricity which do not change significantly compared from the beginning of the test to the end result of the performance testing. The lubrication performance of Maxima XTEND Handpiece Maintenance System on the testing handpieces is similar to lubrication performance of the STATMATIC 31 Handpiece Maintenance Unit on the testing handpieces. Therefore, Handpiece Headquarters believes the performance of Maxima XTEND Handpiece Maintenance System is as safe and effective as predicate device.

i- Safety and effectiveness of the device:

Maxima XTEND Handpiece Maintenance System is as safety and effectiveness as the predicate device as cited above.

j- Biocompatibility

Maxima XTEND Handpiece Maintenance System is used in Dental back office, there is no patient contact with this device. Therefore, there is no biocompability study for this device.

The Lubricant used for this device is the “Maxima Handpiece Cleaner & Lubricant” has been previous cleared under 510(k) # K113674. The chemical components used for this lubricant have already been incorporated in legally marketed device and have a demonstrated history of biocompatibility.

k- Conclusion:

The design and operation of this product has a similar intend of use, similar principles of operation, and similar technological characteristics as previous cleared devices: STAMATIC 31 Handpiece Maintenance Unit 510(k) # K073319.

In addition, similar design characteristic features such as number of handpiece coupling connections, connection to pressurized air supply, similar individual cycles time per instrument, similar push button operation, similar corrosion resistant material to build the machine, and an addition built in maintenance chuck-nozzle for cleaning and maintenance of dental turbine chucks.

Handpiece Headquarters believes that this Maxima XTEND Handpiece Maintenance System is substantially equivalent to the claimed predicate device.